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Original Article

Precise puncture combined with simplified percutaneous vertebroplasty to treat osteoporotic vertebral compression fractures: a comparative analysis with conventional percutaneous vertebroplasty

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Abstract: Objective: To investigate the feasibility and clinical efficacy of precise puncture combined with simplified percutaneous vertebroplasty (PVP) for treating osteoporotic vertebral compression fractures (OVCF). Methods: A total of 82 patients with single-segment osteoporotic vertebral compression fractures (OVCF) treated with PVP from Dec. 2016 to Nov. 2018 were retrospectively analyzed. Among the patients, 45 cases in group A accepted precise puncture combined with simplified PVP, and 37 cases in group B underwent conventional PVP. The operative time, the number of intraoperative fluoroscopy, vertebral height restoration, postoperative bone cement distribution and bone cement leakage were observed and compared. The pain relief and improvement of quality of life (QOL) were assessed by visual analog score (VAS) and Oswestry disability index (ODI). Results: There were no differences in injected cement volume and hospital stays in group A versus group B. The operative time, the number of intraoperative fluoroscopy and material cost were lower in group A compared with group B (P<0.05). After surgery, the VAS scores, ODI, the average vertebral height and Cobb angle were obviously improved and they were significantly different from those before operation (P<0.05). There was no statistically significant difference for VAS scores, ODI, average vertebral height and Cobb angle between groups at different time points. The proportion of patients with bone cement dispersion exceeding the midline of vertebra in group A was significantly higher than that in group B (82.2% vs. 62.1%, P<0.05), whereas the bone cement leakage rate in group A was lower than that in group B (8.9% vs. 27.0%, P<0.05). Patients were followed-up for 12-23 months (mean 17.6 months) after surgery. There were 3 cases (6.6%) of adjacent vertebral fractures in group A and 2 cases (5.4%) in group B. Conclusion: Precise puncture can improve the accuracy of puncture needle through pedicle to vertebral body. It is conducive to obtaining a better diffusion of bone cement across the midline with a lower bone cement leakage rate. Simplified PVP can not only reduce the surgery procedures, shorten the operative time, reduce the X-ray frequency, but also save material cost.

Keywords: Thoracolumbar vertebral fracture, osteoporosis, percutaneous vertebroplasty, precise puncture

Introduction

With aging of the population, the incidence of osteoporotic vertebral compression fracture (OVCF) is increasing year by year. The pain symptoms induced have seriously affected the self-care ability and quality of life (QOL) of elderly patients [1]. As a mature minimally invasive technique, percutaneous vertebroplasty (PVP) has been widely used in many countries. It has become one of the quick and effective methods for treatment of OVCF, due to the advantages of simple operation, rapid relief of pain, recovery of vertebral height, improvement of kyphosis, fewer X-ray exposure, etc. [1-5]. Polymethyl methacrylate (PMMA) is infused directly after successful puncture through the pedicle channel. The steps of establishing balloon channel and intravertebral balloon dilation are omitted. Therefore, intraoperative X-ray frequency and material cost are reduced dramatically. High bone cement leakage rate during PVP is the biggest concern clinically. Young et al. found that the bone cement leakage rate during PVP was up to 76% [3]. Spinal surgeons attempted to improve conventional PVP, such as using the percutaneous curved vertebroplasty technique [4], adopting high viscosity bone cement [5] and applying vertebral gelatin sponge debris pre-perfusion [6].

All approaches above remarkably reduced bone cement leakage. In fact, the most direct and effective way to reduce the bone cement leakage rate is to achieve a precise puncture to avoid the cracked vertebral cortex as far as possible. Because of the low resistance in the ruptured area, bone cement diffusion is more likely to occur during perfusion, thus resulting in cement leakage [2]. How to precisely puncture the pedicle without using O-arm, CT or other large navigation equipment? In this study, the anatomical site of vertebrae was used to achieve precise puncture, and PVP procedures were further simplified. A comparison with conventional PVP was given to show its advantages in improving the puncture accuracy and reducing the bone cement leakage.

Materials and methods

General information

A total of 82 patients with single-segment OVCF received PVP in Harrison international peace hospital of Hengshui City from Dec. 2016 to Nov. 2018 were retrospectively analyzed. Patients were divided into two groups according to the surgical procedure they accepted. Group A (45 cases) accepted precise puncture combined with simplified PVP and group B (37 cases) underwent conventional PVP. Written informed consent forms were obtained from all included patients. The study was approved by the hospital's medical ethics committee (No. 2021-184). All the patients were followed up for one year. Those patients were adopted with routine out-patient clinic appointment, returning visit or telephone follow-ups at an interval of three months.

Inclusion and exclusion criteria

Inclusion criteria: (1) Local tenderness, percussion pain and other typical clinical manifestations; (2) Fresh vertebral compression fracture, from injury to surgical treatment <2 weeks; (3) BMD T value (-2.5 SD), in compliance with the diagnosis criteria of osteoporosis; (4) Clinical follow-up >12 months.

Exclusion criteria: (1) Old vertebral compression fractures, vertebral tuberculosis or tumor; (2) Coagulation disorders, recent infection and inflammatory reaction; (3) Vertebral bursting fracture, damage in posterior wall of vertebrae or lower extremity nerve symptom confirmed by CT scan.

Imaging examination

All patients were given routine X-ray, CT scan and MRI examinations after admission. The position of fractured vertebrae, the degree of vertebral height loss and the angle of local kyphosis were roughly determined by X-ray. CT scan determined whether the anterior edge of vertebrae was damaged, whether the posterior wall was intact and whether the fractured fragments were invasive to the spinal canal. The trajectory of the puncture needle into pedicle was recorded on the cross section, and optimal abduction angle was measured (**Figure 2B**). Fresh or concealed fractures were diagnosed by MRI based on the signal changes in the vertebra (**Figure 2A**).

Surgical procedure

All surgeries were completed by the same senior surgeon (Dr. Zhang). Patient was kept in a prone position. A cushion was put under the chest and hip to suspend the abdomen. The diseased vertebral body was positioned with C-arm X-ray. Perspective position was adjusted to equate the distance of pedicle projection on both sides from the spinous process. Thus, the upper and lower edges of the vertebrae were in a straight line. The puncture site was located at 2-2.5 cm beside the apical spinous process. Cut the skin at the puncture site longitudinally, approximately 4-5 mm. Vertebrae were punctured with vertebroplasty system (Shanghai Kinetic Co., Ltd, China) through unilateral pedicle.

Group A: Puncture needle (2.5 mm in diameter) was positioned in the upper outer edge of the vertebral pedicle. An insertion was made in accordance with the optimal abduction angle. Three reference points, including the posterior wall of the pedicle, middle of the pedicle and junction of the vertebral body, were sequentially passed through on positive and lateral images (**Figure 1A-D**). Then, the needle entered the vertebral body. Needle tip in lateral image

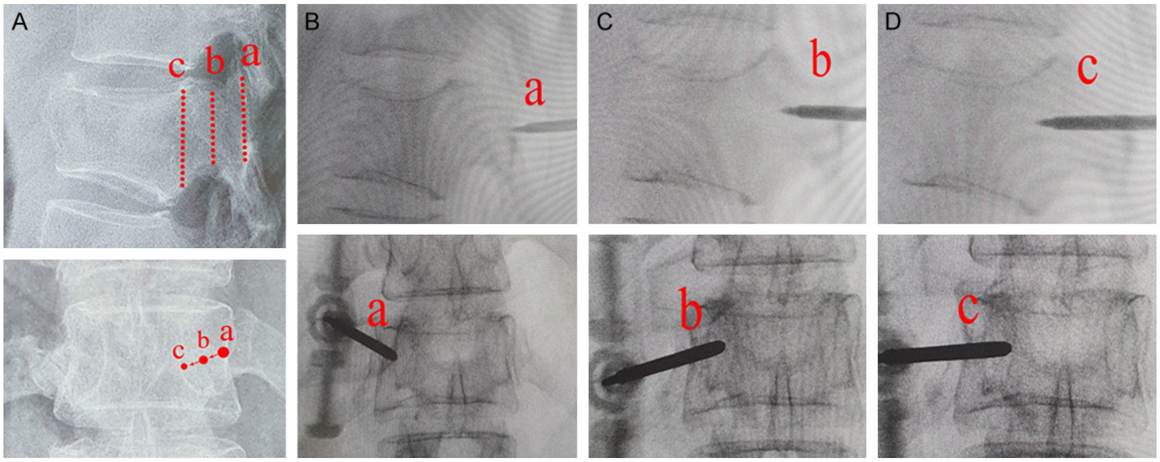

Figure 1. Three reference points were sequentially passed through on positive and lateral images. A. Three reference points (a, b, c) corresponding to the positive and lateral radiographs. B. Posterior wall of the pedicle-outer upper edge of pedicle projection (a). C. Middle segment of the pedicle-midpoint of pedicle projection (b). D. The transition of pedicle and vertebral body-inner lower edge of pedicle projection (c).

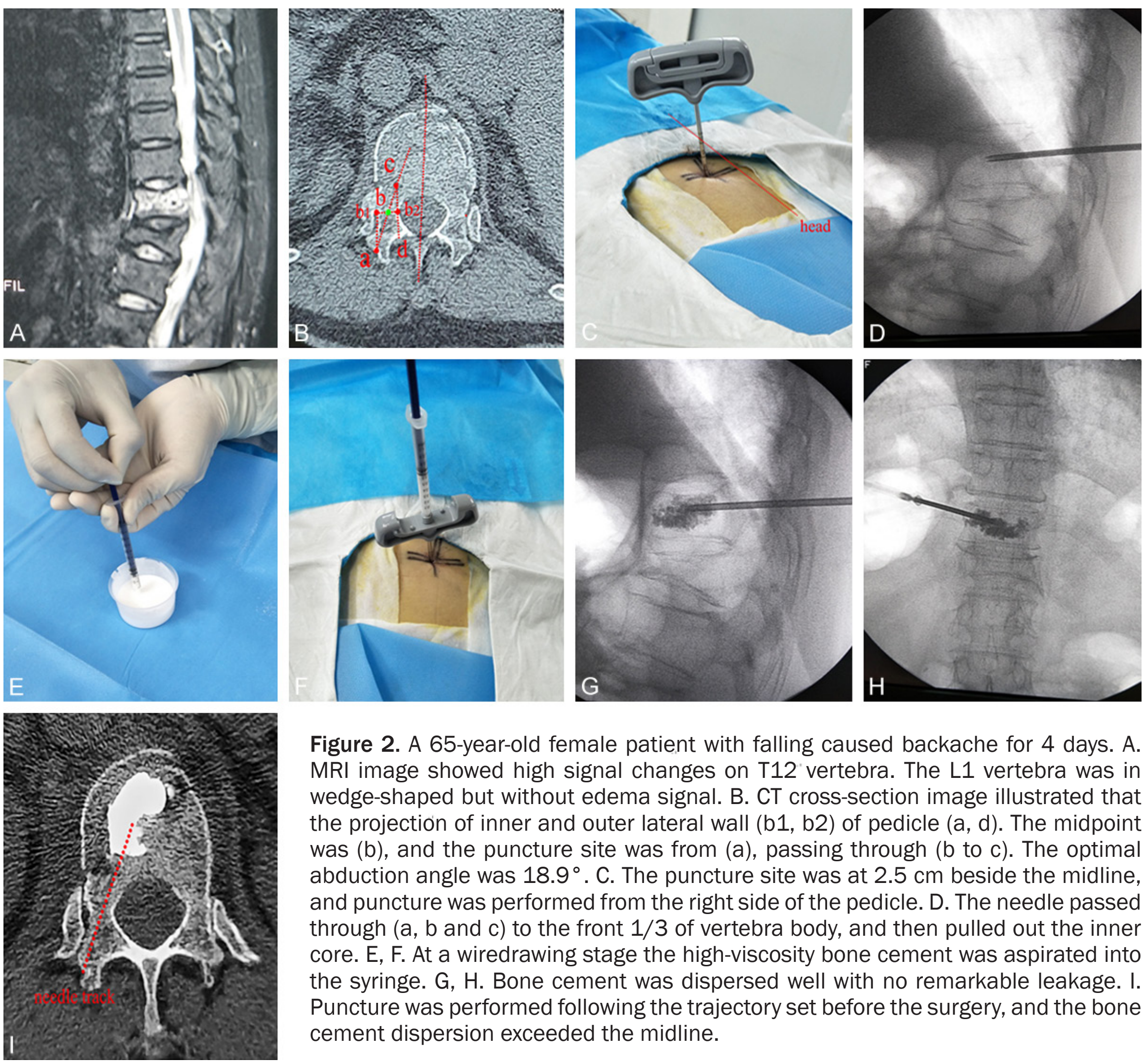

Figure 2. A 65-year-old female patient with falling caused backache for 4 days. A. MRI image showed high signal changes on T12 vertebra. The L1 vertebra was in wedge-shaped but without edema signal. B. CT cross-section image illustrated that the projection of inner and outer lateral wall (b1, b2) of pedicle (a, d). The midpoint was (b), and the puncture site was from (a), passing through (b to c). The optimal abduction angle was 18.9°. C. The puncture site was at 2.5 cm beside the midline, and puncture was performed from the right side of the pedicle. D. The needle passed through (a, b and c) to the front 1/3 of vertebra body, and then pulled out the inner core. E, F. At a wiredrawing stage the high-viscosity bone cement was aspirated into the syringe. G, H. Bone cement was dispersed well with no remarkable leakage. I. Puncture was performed following the trajectory set before the surgery, and the bone cement dispersion exceeded the midline.

reached the front 1/3 of vertebrae, and in a positive image it was close to the midline of the vertebra. Inner core of the puncture needle was pulled out. The prepared high-viscosity bone cement (Tianjin Institute of Synthetic Materials Industry, China) was aspirated with a 2 ml injector and infused slowly into the vertebral body while wire drawing. X-ray was performed once while 0.5 ml cement was infused. An infusion was stopped when bone cement diffused to the upper or lower edge of vertebrae or to the anterior edge of cortex (**Figure 2C-H**). Once the bone cement had hardened, the puncture needle was removed.

Group B: Puncture needle was inserted at an abduction angle of 25-35° to reach the outer upper edge of pedicle projection (left-side puncture at the 2 o'clock position, and right-side puncture at the 10 o'clock position). Once X-ray showed that the needle had reached the middle of vertebrae through pedicle, the needle core was pulled out. The guidewire was insert, and a working channel (4.0 mm in diameter) along the guidewire was then establish. High-viscosity bone cement was slowly infused into vertebrae from the catheter. The infusion was discontinued after bone cement was diffused evenly. After removing the cannula, the patient was observed for 10 min and returned to the ward if there was no discomfort.

Evaluation parameters

The primary indexes were as follows: the operative time, the number of intraoperative fluoroscopy, injected cement volume, material cost and hospital stays were recorded. The secondary indexes were as follows: X-ray and CT scan were taken 1 day after surgery. The diffusion and leakage of bone cement in vertebra were observed. Vertebral body height and local Cobb angle were measured before and after surgery. Pain relief was evaluated with visual analogue scale (VAS) scores (10 points) [4]. QOL and self-care ability was assessed with Oswestry disability index (ODI) [7].

Vertebral body height: On the lateral radiograph, the distance between the upper and lower endplates of the anterior and midline of the vertebral body was measured respectively [7]. The average vertebral height = (anterior vertebral height + median vertebral height)/2. Bone cement dispersion exceeding the midline: A midline was drawn on the CT cross-section of the film to observe whether the bone cement dispersion exceeded the midline (**Figure 2I**).

Cobb angle: On the lateral radiograph, straight lines parallel to the vertebral endplate were drawn respectively on the upper edge and lower edge of the vertebral body next to the diseased vertebra. The intersection angle of the two straight lines was the Cobb angle.

Statistical analysis

All statistical analyses were conducted using SPSS (Version 20.0; IBM, Chicago, IL, USA). The measurement data were expressed by mean ± standard deviation. One-way ANOVA followed by a post hoc. Fisher's least significant difference (LSD) test was used to analyze the data among three groups. And T test was used to detect the differences between the two groups. The counting data were expressed by percentage. An χ^2 test was used to compare between two groups. Two-sided *P*-values of <0.05 were considered statistically significant.

Results

Comparison of general data

There was no significant difference between the two groups in baseline data including age, sex, injury time, bone mineral density (BMD) and fracture location (P>0.05), so the two groups are comparable. See **Table 1**.

Comparison of operative time, number of intraoperative fluoroscopy and material cost

In terms of operative time, the number of intraoperative fluoroscopy and material cost, group A was significantly lower than group B (P<0.05). There were no significant differences in injected cement volume and hospital stays in group A versus group B (P>0.05). See **Table 2**.

Comparison of VAS scores and ODI

The VAS scores and ODI decreased significantly in both groups after surgery (P<0.05), and they were significantly different from those before operation. There was no significant difference between the groups (P>0.05). Compared with preoperative values, the average vertebral height and Cobb angle were significantly improved in both groups after surgery

Table 1. Baseline characteristics of the two groups

Group	Gender		Age (years)	Injury time (days)	BMD T score	Fracture location (cases)		
	male	female				thoracic	Thora-columbar	lumbar
Group A (45 cases)	15	20	67.5±9.2	5.3±2.2	-2.8±0.5	7	31	7
Group B (37 cases)	11	26	68.3±9.8	4.6±2.0	-3.0±0.6	8	24	5
t/X^2 value	1.343		0.380	1.493	1.646		0.515	
P value	0.246		0.704	0.139	0.103		0.773	

Table 2. Comparisons of intraoperative data between the two groups

Group	Operative time (min)	Intraoperative fluoroscopy times	Injected cement volume (ml)	Material cost (RMB)	Hospital days (days)
Group A (45 cases)	36.5±5.3	26.9±3.2	3.6±0.8	7629.5±116.5	4.8±0.9
Group B (37 cases)	42.2±6.7	34.3±4.4	3.4±0.7	9813.2±149.6	4.6±0.8
t value	4.301	8.804	1.191	73.913	1.052
P value	<0.001	<0.001	0.237	<0.001	0.296

Table 3. Comparisons of VAS score and ODI between the two groups

Group	VAS score			ODI (%)		
	preoperative	3 months postop	1 year postop	preoperative	3 months postop	1 year postop
Group A (45 cases)	7.8±1.7	3.4±1.1*	2.6±0.9*	62.3±9.4	29.5±4.3*	24.6±3.2*
Group B (37 cases)	7.6±1.5	3.3±1.2*	2.7±0.8*	61.0±9.1	27.9±4.1*	23.4±3.0*
t value	0.558	0.393	0.526	0.632	1.712	1.637
P value	0.577	0.695	0.600	0.529	0.091	0.106

Note: Compared with those before operation, *P<0.05.

Table 4. Comparisons of average vertebral height and Cobb angle between the two groups

Group	Average vertebral height (mm)			Cobb angle (°)		
	preoperative	3 months postop	1 year postop	preoperative	3 months postop	1 year postop
Group A (45 cases)	16.5±3.3	25.7±4.0*	24.9±3.8*	25.3±3.8	16.7±2.8*	17.3±2.9*
Group B (37 cases)	17.1±3.5	26.1±4.3*	25.3±4.0*	24.4±3.6	16.3±3.0*	17.0±3.2*
t value	0.797	0.435	0.463	1.092	0.623	0.440
P value	0.427	0.664	0.644	0.278	0.534	0.658

Note: Compared with those before operation, *P<0.05.

(P<0.05). And there was no statistically significant difference between the groups at different time points (P>0.05), as shown in **Tables 3** and **4**.

Comparison of bone cement dispersed, cement leakage and adjacent vertebral fractures

The proportion of patients with bone cement dispersion exceeding the midline of vertebra in group A was significantly higher than that in group B (82.2% vs. 62.1%, P<0.05), whereas the bone cement leakage rate in group A was lower than group B (8.9% vs. 27.0%, P<0.05). Patients were followed up for 12-23 months (mean 17.6 months) after surgery. There were 3 cases (6.6%) of adjacent vertebral fractures occurred in group A and 2 cases (5.4%) in group B (P>0.05). See **Table 5**.

Discussion

For PVP technique, complications of intraoperative puncture and bone cement leakage have been increasingly reported [8-10]. Thuse, it is vital to decrease intraoperative complications.

Table 5. Conditions of bone cement dispersed, cement leakage and adjacent vertebral fractures

Group	Bone cement dispersed surpass the midline (%)		Cement leakage rate (%)		Adjacent vertebral fractures (cases)	
	Yes	No	Yes	No	Yes	No
Group A (45 cases)	37 (82.2%)	8 (17.8%)	4 (8.9%)	41 (91.1%)	3 (6.6%)	42 (93.4%)
Group B (37 cases)	23 (62.1%)	14 (37.9%)	10 (27.0%)	27 (73.0%)	2 (5.4%)	35 (94.6%)
X^2 value	4.162		4.718		0.062	
P value	0.041		0.030		0.803	

It is reported that the site and trajectory of the puncture needle not only determine the safety during surgery, but are also directly associated with the leakage rate of bone cement [11-13]. In the past, the abduction angle and puncture trajectory of puncture needle mainly depended on the experience of surgeons. However, muscle thickness of the lower back of patients, as well as pedicle transverse and sagittal diameter width are different; the success rate of puncture will be affected once deviation of the puncture site or puncture angle occurs [14]. Therefore, the precise puncture of PVP is particularly important. In this study, CT images were used to measure and obtain relevant data (group A). Thus, the optimal abduction angle and puncture needle trajectory in vertebrae were determined. Under the monitoring of X-ray during surgery, a puncture needle with a diameter of 2.5 mm was adopted to precisely pass through 3 reference points (a, b, c) of the pedicle. As a result, the puncture needle was always traveling in cancellous bone with uniform texture, and high-viscosity bone cement was infused slowly with an injector when the puncture needle reached the front 1/3 of the vertebrae. During surgery, the precise puncture was conductive to avoiding damaged region of the anterolateral wall of vertebra, so that the bone cement was infused away from the fracture line. Thus, bone cement leakage was effectively prevented.

A puncture needle of 2.5 mm in diameter was convenient to adjust the angle and increase the passing ability in pedicle. Operating steps and material cost was reduced without using a secondary cannula. A graduated injector instead of an injection catheter can more accurately grasp the injection volume of bone cement. Comparison with conventional PVP (group B) showed that this technique is intimately associated with reduced duration of surgery (36.5 min vs. 42.2 min), intraoperative X-ray frequency (26.9 times vs. 34.3 times) and material cost (7629.5 vs. 9813.2). More importantly, bone cement leakage was lower (8.9% vs. 27.0%). In group A, a small amount of air (0.7 ml) in the puncture cannula was likely to enter the vertebral body while bone cement was infused. However, no discomfort symptoms were observed in any patients. It was believed that the air entering vertebrae might diffuse from the vertebral tissue into the soft tissue without air embolism. Bone cement pulmonary embolism [9] and cerebral fat embolism [15] were reported clinically in literature, and no instances of air embolism were reported.

It was reported that the dispersion status of bone cement was closely correlated with biomechanical stability of vertebral body and postoperative efficacy [16, 17]. Li et al. [16] believed that the distribution of bone cement in vertebrae may affect the clinical effect after PVP procedure. The VAS scores of patients with bone cement dispersion tending to one side were significantly higher than those closing to the midline. Therefore, it is recommended that the bone cement should be dispersed exceeding the midline. Molloy et al. [17] confirmed through biomechanics that the strength of the vertebral body can be restored by the volume of bone cement injected to 3.5 ml. The vertebral mechanical stability with bone cement dispersing to one side was poor, but the occurrence of vertebral recompression was not influenced. In this study, symptoms of local pain were markedly alleviated in group A and group B, and daily life and self-care were significantly improved. The rate of bone cement dispersal exceeding the midline in group A under precision puncture was significantly higher than that of group B (82.2% vs. 62.1%). No recompression of the cemented vertebral body occurred in any patients during follow-up. There were 3 cases (6.6%) adjacent vertebral fractures in group A and 2 cases (5.4%) in group B, with no significant differences. This fully demonstrates that the overall efficacy of these two minimally invasive techniques is the same, but the precise puncture method can make the channel closer to the midline of the vertebral body, which is conducive to the high-viscosity bone cement to be evenly dispersed in the vertebral body, and ultimately, make the vertebral body strengthening more uniform.

Intraoperative bone cement leakage is associated with a variety of factors, such as fracture severity grade, integrity of endplate and cortex, cement injection stage, injected cement volume, cement viscosity, injection techniques, and puncture accuracy [2, 4, 5, 9-13]. Zhu et al. [18] found that among the many related factors of bone cement leakage, fracture severity and bone cement injection were the two strongest independent risk factors for leakage. During the operation, it is difficult for the surgeon to control the optimal amount of bone cement; small injection volume may lead to poor postoperative effect [19], and excessive injection volume is likely to cause irreversible bone cement leakage [18, 20]. In order to restore the mechanical strength of the vertebral body, Liebschner et al. [21] recommended that the volume of bone cement in the upper thoracic vertebrae should be 2.5-3.0 ml, thoracolumbar vertebrae 3-4 ml, and lower lumbar vertebrae 5-6 ml. To reduce the bone cement leakage rate, high-viscosity bone cement was used in both groups, and the injection volume was controlled as 3.4-3.6 ml, combined with an intraoperative precision puncture. The leakage rate was reduced to 8.9%, which was significantly lower than those reported in studies of Saracen et al. [9] and He et al. [12] (41.7% and 13.6%, respectively).

This study has some limitations. First, the sample size was not enough. Second, only short-term indicators were evaluated. Third, the mechanisms of precise puncture were not mentioned. Therefore, conducting a prospective, multicenter, randomized controlled and large-sample clinical study on precise puncture combined with PVP for treating OVCF is warranted to provide more evidence for treatment of OVCF.

In conclusion, by adopting intraoperative precision puncture, the accuracy of puncture is dramatically improved so that the bone cement dispersion could exceed the midline better, and the bone cement leakage rate is reduced. By using the simplified PVP technique, the operation steps and intraoperative X-ray frequency are reduced, the surgery duration is shortened, and material cost is decreased. No significant difference is observed in vertebral height recovery and Cobb angle improvement compared with conventional PVP.

Disclosure of conflict of interest

None.

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